CPME/AD/EC/14112014/083_Final/EN

On 14 November 2014, the CPME Executive Committee adopted the 'CPME Response to the Independent Review of the European Standardisation System' (CPME 2014/083 FINAL)

CPME Response to the Independent Review of the European Standardisation System

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.[1]

Please find the draft CPME response included in the questionnaire below in green font. It is not mandatory to respond to any question apart from those marked *. Please include all corrections or additions as tracked changes.

Consultation questionnaire

1. Background

The Commission (EC) strategic communication "A strategic vision for European Standards" (COM(2011)311 final) and the Regulation (EU) No 1025/2012 on European Standardisation form the so called Standardisation Package, established with the aim to *"increase the contribution of European standards and other European standardisation deliverables to a better functioning internal market, stimulating growth and innovation, and fostering the competitiveness of EU enterprises, especially SMEs".*

In response to Action 29 of the Communication, EY (Ernst & Young) is carrying out on behalf of "Directorate General for Enterprise and Industry" an Independent Review of the European Standardisation System (ESS). This survey is to collect the opinion of a broad range of stakeholders in order to assess:
- Progress against the strategic objectives, defined by COM(2011)311: speed of the standard setting process, support to competitiveness for European businesses, support to legislation, inclusiveness and support to competitiveness worldwide;
- The impact of the current governance on the performance of the European Standardisation

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41. CPME has also adopted the 'CPME response to the public consultation on investment protection and investor-to-state dispute settlement (ISDS) in the Transatlantic Trade and Partnership Agreement (TTIP)' and the 'CPME response to the public consultation for the own-initiative inquiry of the European Ombudsman towards the European Commission concerning transparency and public participation in relation to the TTIP negotiations'.
More information about CPME's activities can be found under www.cpme.eu

System;
- The overall performance of the ESS and areas where improvements are required.

The European standardisation system (ESS) is understood as a network –and its related processes- of stakeholders active in European standardisation. This includes, in alphabetical order: the European Commission (EC), the industry (and companies in general), Member States, stakeholders representatives and standard setting organisations (European standardisation organisations (ESO) and National standardisation bodies (NSB)).

The processes that are in scope of this questionnaire are: the mandating process (identification of need for standard development, standards developed upon Commission request), the standardisation work performed by ESOs (reception of the request until availability of the standard) and referencing in the OJEU (for mandated standards supporting legislation needs).

All European standard deliverables are in scope of this study, including harmonised standards, with the meaning defined by Art. 2(1c) of Regulation (EU)1025/2012, or "adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation".

This is your opportunity to make your voice heard and to express your views about progress made within the ESS.

When completing this questionnaire, please answer about your own sector, experience, and practical experience about the European Standardisation System. Please base your answers on facts that you have already observed.

2. Information about the questionnaire

The survey is open as of October 20th, 2014, and filled questionnaires needs to be submitted before November 16th, 2014 COB. Filling the survey takes on average 30 minutes. When answering the questionnaire, you have the possibility to come back to previous questions to edit your answers. It is also possible to complete a part of the questionnaire and to finalise it later (note that the same computer and browser must be used, and the cookie must not have been deleted).

In the questionnaire, the following key abbreviations are used:
• EC: European Commission
• ESS: European standardisation system
• ESO: European standardisation organisation (CEN, CENELEC and ETSI)
• NSB: National standardisation body

Depending on the question, the input method will vary:

- "Yes or No" – This statement is the best way for having strong categorisation between stakeholders and is either used for very broad statements or for very accurate questions. Answers to these questions will serve as preliminary statistics and will not be used without deep analysis of other answers (see description below);

- "5-ranked evaluation" – For the assessment of specific goals or targets, the survey identifies 5 levels

of appreciation, such as “very low” to “very high”; “never” to “always” (for frequency only); “very good” to “very bad”.

- “Open comments” – For more complex questions, an open comment is requested, offering more flexibility to respondents.

In case you cannot answer a question, or if a question is irrelevant for you, please skip the question.

This questionnaire is hosted on an independent platform guaranteeing safety of data. The answers collected through this questionnaire will be treated in a confidential way and individual results will not be communicated to any third party. Aggregated results by category will however be used within the remit of the Independent Review.

::

3. General information on the Institution/Organization/Company

* 1. Please identify yourself
(The information provided will only be used for identification purposes and will not be disclosed)

What is the name of your Institution/Organisation/Company?
Standing Committee of European Doctors (CPME)

What is your name (first name + last name)?
Sarada Das

What is your email address?
sarada.das@cpme.eu

* 2. For which country are you responding?
International

3. If relevant, please select the NACE code corresponding to your activity, or the activity you represent:

Q - HUMAN HEALTH AND SOCIAL WORK ACTIVITIES

* 4. To what category does your Institution/Organization/Company belong to?
Please select one

For companies, please indicate the number of employees if it is a SME /For EC/EFTA, please indicate the service / For Other European institutions or agencies, please indicate the institution or agency/ For ESOs, please indicate what ESO/ For the NSBs, please indicate the field of activity/ For other standardisation bodies, please indicate the name/ For Stakeholder organisations or NGOs, please indicate whether it is national or international and the stakeholder group represented/ For others, please specify the involvement within the ESS

Stakeholder organisation or NGO
The Standing Committee of European Doctors (CPME) represents national medical associations across Europe

* 5. Experience in standardisation: How is your organisation involved in the ESS ?

Participates in activities
Buys standards for direct use
Informs others about standards
Other (please specify)

CPME monitors and responds to the activities of the European Standardisation Organisations and the European Commission relating to standardisation affecting the healthcare sector.

* 6. What is the estimated FTEs (full time equivalent) participating in standardisation activities, within your
organisation ?

N/A

* 7. Self-assessment of knowledge about the ESS and standardisation practices in general

Self-assessment
Very high
High
Moderate
Low
Very low

4. Objective "Speed and timeliness" [no CPME response proposed for this section]

Objective "Speed and timeliness", intended as speed of the standardisation process and the time needed for standards to become available. It is understood that this objective is achieved if standards are available in a timely matter (when needed).

The timeframe considered for speed and timeliness is the time lapse between the identification of the standardisation need (informally by industry or formally through a EC mandate) and the availability of the standard. In the case of harmonised European standards, we understand that the time needed for publishing the reference of a standard in the Official Journal of the European Union (OJEU) also needs to be taken into account.

8. Do you consider that standardisation deliverables within the ESS are available in a timely manner?

Yes
No
No opinion/cannot answer

9. According to your experience, to what extent has the ESS achieved the following goals? Also, how do you expect the ESS to achieve those goals?

Please give a rating from "very high" to "very low" to achievements under each heading. Please also explain the reasons of your rating and the issues identified (in the case of "moderate", "low", "very low" rating). Please provide examples and concrete cases if possible. If you see any other achievement, please specify.

	Achievements to date (rating: Very high – High – Moderate – Low - Very low)	Expected achievement (rating: Very high – High – Moderate – Low - Very low)
Early indication of forthcoming Union		

policy needs (EC needs only), through the Union Work Programme		
Timely start of standardisation activities		
Prompt involvement of the stakeholders		
Overall Speed of the standards development process		
Quick publication of available standards in the OJEU (for harmonised standards only)		

Please explain the reasons of your rating and the issues identified (in the case of “moderate”, “low”, “very low” rating). Please provide examples and concrete cases if possible. Please also specify any other achievements

10. Has the interest in speed decreased the quality of the standard? Also, what is the expected impact?

	Impact to date (rating: Very high – High – Moderate – Low - Very low)	Expected impact (rating: Very high – High – Moderate – Low - Very low)
Impact of the improved interest in speed on quality of standards		

Additional comments

11. Should research institutes be further involved in standardisation activities, to ensure early start of standardisation activities? Please explain the expected impact/outcomes.
Yes
No
No opinion/cannot answer
Additional comments

12. From your perspective, is the achievement of the objective “Speed and timeliness” different in the following situations?

	Yes	No	No opinion
Standards for services compared to standards for products			
Standards triggered by mandate compared to standards triggered by industry			

Additional comments

13. Please describe any bottlenecks to the “timely availability” of standards, that you have experienced. If any, please explain how to overcome these bottlenecks.

5. Objective "Competitiveness of European businesses, in the internal market" [no CPME response proposed for this section]

14. In your opinion, does the ESS provide enough support to the competitiveness of European companies in the Internal market (by removing conflicting national standards, facilitating free movement of goods and providing state of art specification in wide range of technical domains)?

Yes
No
No opinion/cannot answer

15. According to your experience, to what extent has the ESS achieved the following goals? Also, how do you expect the ESS to achieve those goals?

Please give a rating from “very high” to “very low” to achievements under each heading. Please also explain the reasons of your rating and the issues identified (in the case of “moderate”, “low”, “very low” rating). Please provide examples and concrete cases if possible.

	Impact to date (rating: Very high – High – Moderate – Low - Very low)	Expected impact (rating: Very high – High – Moderate – Low - Very low)
Facilitating cross-border activities and trade in the Internal market		
Facilitating the market penetration of innovative technologies		
Reducing the production costs for companies		
Increasing interoperability of products		
Developing standard deliverables being market relevant		
Facilitate access to EU market for EU SMEs		
Enhancing companies’ growth (e.g. market share) and competitiveness		

Please explain the reasons of your rating and the issues identified (in the case of “moderate”, “low”, “very low” rating). Please provide examples and concrete cases if possible. Please also specify any other achievements

16. Have you experience any situation in which, in your opinion, the ESS failed to support competitiveness in the single market?

Yes
No
No opinion/cannot answer

Additional comments

17. From your perspective, is the achievement of the objective "Competitiveness of European business in the internal market" different in the following situations?

	Yes	No	No opinion
Standards for services compared to standards for products			
Standards triggered by mandate compared to standards triggered by industry			

Additional comments

18. Based on your experience, what changes (if any) do you recommend to be made to increase the contribution of the ESS to the competitiveness of European companies in the single market?

6. Objective "Support to EU policy and legislation"

19. Does the ESS act as an effective support to EU legislation and policies?

Yes
No
No opinion/cannot answer

20. According to your experience, to what extent has the ESS achieved the following goals? Also, how do you expect the ESS to achieve those goals?

Please give a rating from "very high" to "very low" to achievements under each heading. Please also explain the reasons of your rating and the issues identified (in the case of "moderate", "low", "very low" rating). Please provide examples and concrete cases if possible. If you see any other achievement, please specify.

	Impact to date (rating: Very high – High – Moderate – Low - Very low)	Expected impact (rating: Very high – High – Moderate – Low - Very low)
Early identification of standardisation needs supporting policies and legislation		
Improved safety of products		
Use standards for facilitating compliance with directives and regulations		

Please explain the reasons of your rating and the issues identified (in the case of "moderate", "low", "very low" rating). Please provide examples and concrete cases if possible. Please also specify any other achievements

21. What is the system's ability to respond to an increased demand for standards to support EU legislation and policies (e.g. increased standardisation requests from the Commission to the ESOs)? What, if any, steps need to be taken now to ensure the readiness of the system?

Please also explain the reasons of your rating and the issues identified (in the case of "moderate", "low", "very low" rating). Please provide examples and concrete cases if possible.

Very High
High
Moderate
Low
Very Low
No opinion/cannot answer

Additional comments

22. From your perspective, is the achievement of the objective "Support to EU legislation and policies" different in the following situations?

	Yes	No	No opinion
Standards for services compared to standards for products	X		

Additional comments
When it comes to healthcare services, the division of competences between European Union, Member States and, as applicable, professional bodies at national level, precludes action by the European Standardisation System. Article 168 of the Treaty on the Functioning of the European Union provides that Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, which includes the management of health services and medical care and the allocation of the resources assigned to them. This is also reflected in Directive 2006/123/EC on services in the internal market, i.e. healthcare and pharmaceutical services are exempted from its scope of application. Any action aiming to support EU legislation and policies must respect this regulatory framework. CPME reiterates that where national legislation awards the competence to adopt professional regulations, ethical codes, and clinical guidelines and recommendations to the regulatory bodies of the profession, it is crucial to refrain from adopting standards which conflict with this regulatory framework. Clinical guidelines and recommendations developed in the medical profession ensure the best possible coherence, expertise and legitimacy, while at the same time respecting the principles of clinical independence and professional autonomy to safeguard that every patient can be provided the most suitable treatment for their individual case.

23. Based on your experience, what (if any) changes do you recommend to be made to increase the contribution of the ESS as support to EC legislation and policies?

7. Objective "Inclusiveness of the ESS"

Objective "Inclusiveness of the ESS", intended as the ability of the processes in the ESS to involve a wide range of participants (representative of businesses of all sizes, consumers, other societal stakeholders such as trade unions, environmental NGOs, representatives of elderly and disabled people) and develop close cooperation among partners (ESOs, NSBs, public authorities at EU and national level)

24. Do you consider the ESS to be inclusive?

Yes
No
No opinion/cannot answer

25. Did improvement in speed impair the inclusiveness of the ESS? Also, what is the expected impact?

	Positive/negative impact to date (rating: Very high – High – Moderate – Low - Very low)	Expected positive/negative impact to date (rating: Very high – High – Moderate – Low - Very low)
Impact that the interest in speed has on inclusiveness		

26. According to your experience, to what extent has the ESS achieved the following goals? Also, how do you expect the ESS to achieve those goals?

Please give a rating from "very high" to "very low" to achievements under each heading. Please also explain the reasons of your rating and the issues identified (in the case of "moderate", "low", "very low" rating). Please provide examples and concrete cases if possible. If you see any other achievement, please specify.

	Achievements to date (rating: Very high – High – Moderate – Low - Very low)	Expected achievement (rating: Very high – High – Moderate – Low - Very low)
Representation of SMEs views in the ESS		
Representation of societal stakeholders perspective in the ESS		
Participation of research community in the ESS		
Participation of Member States' pubic authorities in the ESS		

Please specify other achievements you would have identified

27. Is the range of participants involved in the ESS standard setting processes (from the need definition until the availability of the standard) wide enough?

Yes
No
No opinion

If not, please identify any relevant groups that are not sufficiently included and indicate how they could be better involved
CPME, as well as other representative organisations of the medical profession, has repeatedly presented its objections regarding initiatives by the European Commission and European Standardisation Organisations relating to the standardisation of healthcare services. These objections have not been reflected in the consequent action taken by these parties, nor was there any meaningful attempt to involve the medical profession's representative organisations in the process identifying the need for standard development.

28. From your perspective, is the achievement of the objective "Inclusiveness" different in the following situations?

	Yes	No	No opinion
Standards for services, compared to standards for products			
Standards triggered by mandate, compared to standards triggered by industry			

Additional comments
As set out above, the division of competences between the European Union, Member States and, as applicable, professional bodies at national level as set out in EU and national law precludes the European Commission and European Standardisation Organisations from adopting standards for healthcare services. The European Standardisation System should pro-actively involve all relevant parties in any action which explores the development of a standard and follow their recommendations to ensure that action taken respects the regulatory framework of the healthcare sector.

29. Please describe any bottlenecks to the inclusiveness of the ESS that you have experienced. If any, please explain how these bottlenecks could be overcome in your opinion.
There is a lack of transparency and access to standardisation processes, e.g. in relation to the work of technical committees of European Standardisation Organisations. Access to the work of technical committees can be achieved only via the National Standardisation Bodies participating in the relevant technical committee, which in turn often make the participation of stakeholders such as the medical profession subject to prohibitive fees.

8. Objective "Competitiveness of European businesses at a global level" [no CPME response proposed for this section]

Objective "Competitiveness of European businesses at a global level", intended as support in reaching foreign market and establishing industry partnerships around the globe

30. Does the ESS supports the competitiveness of EU companies in the global arena?

Yes
No
No opinion/cannot answer

31. According to your experience, to what extent has the ESS achieved the following goals? Also, how do you expect the ESS to achieve those goals?

Please give a rating from "very high" to "very low" to achievements under each heading. Please also explain the reasons of your rating and the issues identified (in the case of "moderate", "low", "very low" rating). Please provide examples and concrete cases if possible.

	Achievements to date (rating: Very high – High – Moderate – Low - Very low)	Expected achievement (rating: Very high – High – Moderate – Low - Very low)
Facilitating market access outside EU/EEA		
Facilitating the establishment of business partnerships around the globe		
Recognition of European standards at international level		
Recognition of international standards at European level		

Please specify any other achievements

32. From your perspective, is the achievement of the objective "Competitiveness of European business at global level" different in the following situations?

	Yes	No	No opinion
Standards for services, compared to standards for products			
Standards triggered by mandate, compared to standards triggered by industry			

Additional comments

33. Based on your experience, what changes (if any) do you recommend to be made to increase the contribution of the ESS to the competitiveness of European companies at global market?

9. Governance of the ESS [no CPME response proposed for this section]

"The governance of the ESS" is defined as: the systems of management and control of the ESS, its rules and operating procedures, and the bodies (boards, committees, directors that govern it.

Overall speed, efficiency of the communication and quality of the ESS

34. Do you consider the ESS to be well-governed?

Yes
No
No opinion

If not, which elements are not well-governed and which corrective actions would you suggest ?

35. Are the interaction and the communication flows among actors (EC, the ESOs, Member States, NSBs and other stakeholders) satisfactory?

Yes
No
No opinion

If not, please describe which improvements could be made and between what actors

36. Do you experience any avoidable administrative burden associated with your role in the ESS, or at specific parts of the process in which you are involved?

Yes
No
No opinion/cannot answer

If you do, which are the bottlenecks in the process and which corrective actions would you suggest?

37. Is the Comitology procedure , introduced by Art. 10 of the Regulation(EU) No1025/2012, an effective system to ensure the timeliness, transparency and inclusiveness of the ESS during the mandating process?

	Yes	No	No opinion
Timeliness			
Transparency			
Inclusiveness			

If the answer to one of the previous questions is "no", which improvements could be made?

38. Have you identified issues in the delay for national implementation of European standards?

Yes

No
No opinion/cannot answer

Additional comments

10. Governance of the ESS

Active participation of all the stakeholders

39. Does the current governance ensure the actual and active participation of all the stakeholders involved in the process (in particular the ones referred to in Annex 3, being SMEs, consumers, stakeholders representing environmental interests and social interests)?

Yes
No
No opinion

If not, which improvements could be made?
Any proposed action relating to healthcare services should pro-actively be presented for consultation to all relevant parties, on the basis of whose views a decision should be made as to whether or not there is a need for and benefit of standard development. As set out, CPME does not see a need for or benefit of standards in healthcare services.

40. Does the current ESS governance and ESO guidelines offer the guarantee for effective representation of stakeholders within the process?

	Yes	No	No opinion
Does the current ESS governance and ESO guidelines offer the guarantee for effective representation of stakeholders within the process?		X	
In particular, do you think that current voting rights allow for balanced consensus making?		X	

If the answer to one of the previous questions is “no”, what improvements could be made?
The European Standardisation System must remove all barriers to access for stakeholders and ensure the greatest possible transparency of its work, as well as the pro-active engagement of stakeholders. As regards voting rights and regulations, the outcomes of the recent vote on EN 16372 on aesthetic surgery services developed by a European Standardisation Organisation shows that there is a need to review the voting rules’ definition of ‘consensus’ to ensure that actions adopted are supported by a majority.

41. In your opinion, to what extent can the participation level be related to the level of knowledge and awareness on the importance of standards?

42. Considering your position within the ESS, do you feel sufficiently consulted?

Yes
No
No opinion

If not, please explain the main gaps in the consultative processes and which corrective actions you would suggest
Notwithstanding the competence of individual specialised experts, it is necessary to ensure that stakeholders involved consultative processes fulfil a degree of representativeness in relation to their respective constituencies, so an informed decision can be made as to the actual degree of consensus for the views presented. This will ensure a high quality of contributions.

43. Considering your position within the ESS, do you receive enough information?

Yes
No
No opinion

If not, please explain the main gaps in information provision and which corrective actions you would suggest
There are barriers to the access to information for all processes relating to standardisation initiatives.

44. In the scope of public consultations about draft standards, during the commenting phase (public enquiry):

	Agreement (rating: strongly agree – agree – undecided – disagree – strongly disagree)
You have enough time to analyse and prepare your participation in European standardisation	
You have enough information to analyse and prepare your participation	Disagree
Your input is sufficiently taken into account	Strongly disagree
You receive sufficient feedback/status about comment	Disagree

45. Are you aware of the existence of an appeal procedure?

Yes
No
No opinion

46. If you are aware of the existence of an appeal procedure, have you already used this procedure?

Yes
No
No opinion

47. If you already used the appeal procedure, did it appear to be effective?

Yes
No
No opinion

Other (please specify)
Media reports indicate plans to amend the appeal procedure, thereby weakening the position of societal stakeholders. CPME would welcome more information on this point.

11. Final comments and recommendations

Is the ESS fit for future challenges?

48. What is, in your opinion, the definition of a good quality standard?

49. Based on your previous answer, to what extent does the quality level of European standard deliverables respond to your needs?

Very High
High
Moderate
Low
Very Low
No opinion/cannot answer

Please explain the reasons of your rating and the issues identified (in the case of "moderate", "low", "very low" rating). Please provide examples and concrete cases if possible.

50. Are there any new technical domains which you consider insufficiently covered by European standards (i.e. where European standards are missing/urgently needed?)

51. What are, in your opinion, the reasons that prevent the ESS to expand its scope to these new technical domains?

Please explain the reasons of your rating and the issues identified (in the case of "moderate", "low", "very low" rating). Please provide examples and concrete cases if possible.

	Agreement (rating: strongly agree – agree – undecided – disagree – strongly disagree)
Lack of experts to run new ESO technical committees	
Lack of financial resources to run new ESO technical committees	
Lack of interest of industry or other stakeholders to provide experts	
Lack of cooperation with other specialised standards setting bodies	

Lack of consensus between the different actors of the ESS	
National interests to keep national standards	
Primacy of international standards	
Existence of other bodies developing standards (e.g. Fora and Consortia)	

Please specify any other reasons

52. In a long term perspective (by 2020), the ESS should be able to adapt to a quickly evolving environment and to contribute to the Union's strategic objectives, in the field of industrial policy, innovation and technological development. In order to ensure the relevance of the ESS against the future needs, its effectiveness, efficiency and coverage, which areas of action do you deem as crucial?

Please rate the importance of each area of action from "very high" to "very low".

	Long term interest (rating: Very high – High – Moderate – Low - Very low)
Anticipate the identification of standardisation needs and accelerate the start of the standard development process, in order to promote innovation and prevent other countries/regions to develop competitive advantages	
Promote the involvement of stakeholders and the development of inclusive processes, as means to grant the alignment of standards to market/consumer needs	
Promote cooperation at global and European level, between European and international standardisation organisations including other professional standards setting bodies	
Strengthen the cooperation, coordination and communication flows among standardisation bodies	
Promote awareness on the benefit of standardisation processes for competitiveness and innovation	
Consider organisational and procedural adaptations in the ESO/NSB network to update it with the future needs (with focus on technology convergence)	

Please specify any other

53. Can you identify any barriers or "blocking factors" in the current system and practices, which prevent the full effectiveness and efficiency of the ESS?

54. What do you consider to be the greatest achievements of the ESS?

55. Which are your recommendations for the overall improvement of the ESS?

56. In addition to the answers and comments provided earlier in this questionnaire, please use the following textbox to provide additional comments you might have.

12. Contact for folllow-up

* 57. I accept to be contacted for further discussion about the ESS.

Yes
No